Applicable case law holds that in order for prior art to render a claim obvious under 35 U.S.C. §103(a), the prior art must teach or suggest all of the claimed features and their combination to a person of ordinary skill in the art. In the present case, none of the prior art teaches or suggests injecting only a sealing material into the teat of a cow to form a barrier against infection. Accordingly, no combination of the prior art would result in a system as presently claimed.

As a preliminary matter, Applicants note that two references listing John Dowrick as an inventor are of record in this application, but the rejection refers only to "Dowrick et al" without indicating which of the two references is relied upon in making the rejection. Nevertheless, Applicants have studied each of the Dowrick references and found absolutely no suggestion in either reference to form a barrier against infection using a sealing material that does not include an antibacterial agent.

Both Dowrick references disclose a method for the treatment and control of mammary disorders in which an antibacterial agent is administered to the animal via the intramammary route during the animal's dry period. In US 3,912,806, the antibacterial agent is granulated with a water insoluble non-waxy binding agent. In EPO 271,306, the antibacterial agent is administered in the form of particles suspended in a hydrophobic oily vehicle. The stated objective in both cases is to provide sustained/prolonged release of

the antibacterial agent in the treatment of bovine mastitis. EPO 271,306 at page 2, lines 18 and 19; US 3,912,806 at col. 1, lines 51-62. Thus, contrary to statements in the Office Action, the antibacterial agent is clearly not an optional additive of the composition of Dowrick - it is the main ingredient.

Lazonby discloses a veterinary composition for treatment and/or prevention of mastitis in dry cattle including an antibacterial agent in combination with a non-toxic heavy metal salt. There is absolutely no suggestion in Lazonby to use a sealing material apart from an antibacterial agent.

Since neither the Dowrick references nor Lazonby teach or suggest injecting a sealing material into the teat of an animal without an antibacterial agent, the proposed combination of Dowrick and Lazonby cannot meet the invention as set forth in claim 28.

Moreover, Applicants disagree strongly with the statement in the Office Action that it would be obvious to use a teat sealing material which does not contain an antibacterial agent when treating cows who are healthy. This is because antibacterial dry cow products work in two ways. Firstly, they eliminate bacterial infections which are present at the time of administration. However, an equally important effect of the antibacterial agent is to prevent new infections during the dry period. The use of combined seal and antibacterial formulations to protect the udder implies that neither element is adequately effective when used alone.

Applicants are leaders in the field of teat seal technology. They are expert in methods and formulations available to treat and prevent intramammary infection. Work previously carried out by the Applicants and others in the area of teat seals indicated that a combination of an antibacterial and a seal was needed to prevent intramammary infection. This is also demonstrated by the prior art relied upon by the Examiner. Indeed, many unsuccessful products, such as collar studs, that do not involve use of antibacterial agents have been tried and failed to prevent infection to prevent infection, or even reliably to remain in the teat for the duration of the dry period, in clear contrast to the observed properties of Teat Seal.

The success of the anti-infective free formulation of the present invention is therefore genuinely surprising. From the results shown in Table 1 on page 11 of the description as filed it can be seen that using the seal formulation of the present invention only a 1.9% occurrence of new intramammary infection (IMI) occurs in cows during the dry period in comparison to a 2.5% IMI for a formulation comprising both a seal and an antibacterial.

A further advantage of the seal formulation alone is that there is no risk of contaminating the milk with antibiotics. Antibiotic residues in milk are a serious public health concern and they are increasingly being regarded as a significant promoter of antibiotic resistance among bacteria. The absence of antibiotic from the seal

completely avoids these risks whereas current antibiotic-containing products, by their very nature, promote them.

In view of the foregoing, withdrawal of the rejection of claim 28 under 35 U.S.C. §103(a) is respectfully requested.

Claims 2-8 depend from claim 28 and are submitted to be patentable over the Dowrick references in view of Lazonby for the reasons set forth above as well as for the additional features they recite. For example, none of the foregoing references teaches or suggests a seal formulation containing at least 40% by weight of a heavy metal salt as set forth in claim 3, much less 50% - 75% by weight as set forth in claim 4, or approximately 65% as set forth in claim 5. Seal formulations having heavy metal salt in the above amounts have been found to be effective in preventing intramammary infection for the duration of the dry period. By way of contrast, Lazonby describes a bismuth salt content up to 30% by weight with an undefined degree of efficacy in preventing mastitis infection in dry cows. The efficacy of the teat seal formulation of the present invention is directly attributable to its greater density due to the higher inclusion of a heavy metal salt which results in improved conformity to the internal contours of the teat and reduced erosion once formed thus ensuring the durability of the seal.

Accordingly, withdrawal of the rejections of claims 2-8 under 35 U.S.C. §103(a) is also respectfully requested.

Applicants submit that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

Respectfully submitted,

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